

Application Serial No. 09/753,355  
Amendment dated January 15, 2004  
Reply to Office Action dated October 15, 2003

### **REMARKS**

Claims 16-25 and 27-30 are pending. Claims 16-25 and 27-30 stand rejected.

In this amendment, claims 21, 25 and 30 are amended. Claim 26 is canceled without prejudice. In view of these amendments and/or the remarks below, Applicants submit that this application is now in condition for allowance.

#### **Claim Objections - Language Informalities**

Claim 30 has been objected to as being unclear as to whether only one or both finger tab portions must have the shape stated in the claim. In response, Applicants note that claim 30 depends directly from independent claim 25. Claim 25 recites that the one-piece introducer includes "a first finger tab and a second finger tab." Claim 30 has been amended to recite "the first finger tab and the second finger tab each" so as to be consistent in terminology between the two claims.

#### **Claims 16-20**

Independent claim 16, and its dependent claims 17-20, have been rejected either as being anticipated by Whitney U.S. Patent No. 5,489,273 (claims 16 and 18-20) or as being unpatentable over Whitney in view of Orr U.S. Patent No. 5,263,938 (claim 17). The rejections are respectfully traversed.

Applicants note that claim 16 recites that there is a hinge portion between the finger tab portion and the tub. As recognized in the dictionary, a hinge is "a jointed or flexible device on which a door, lid or other swinging part turns". Webster's Ninth New Collegiate

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Dictionary, at page 572 (Copr. 1983) a copy of which is attached as Exhibit A. As a consequence, it will be seen that the claimed introducer requires that the finger tab portion be able to turn relative to the tube via the hinge. There is no such hinge in Whitney.

In Whitney, there is a very large wing (18 or 20) which is secured to the tube. Each wing has an angled shaped, which results in very large finger gripping portions at the top, and smaller tube-engaging portions at the bottom. Examiner asserts that the area in between the large and small portions (referred to as the "vertical extensions" in the Official Action) defines a hinge portion. Not so.

First, it is noted that the wings are "attached" directly to the sheath (Whitney, col. 3, ll. 8-9), and so there is no disclosure of a hinge between the wings and the tube as required by present claim 16. Further, to split the sheath, finger pressure is applied to squeeze the two wings together (i.e., towards each other). It is the bringing together of the large, upper portions of the wings that causes the smaller, lower portions to pivot apart or separate, thus splitting the sheath. This is described at col. 3, ll. 28 to 41 of Whitney. Were the "vertical extension" between the upper and lower portions of a wing actually a hinge, then the upper portion of each wing would simply rotate relative to its lower portion. As a consequence, the lower portions would not pivot or separate, and the sheath would not be split. At bottom, each wing is a substantial mass of solid plastic, and simply does not include a hinge. Nor would inclusion of a hinge thereon be appropriate, for it would interfere with proper operation and use of the Whitney device.

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In view of the above, it is respectfully submitted that Whitney does not anticipate (nor render obvious) the invention of claim 16 (or its dependent claims 17 through 20), and the rejection thereof should be withdrawn.<sup>1</sup>

**Claims 21-25 and 27-30**

Claims 21-24 stand been rejected as anticipated by Whitney. Independent claim 25 stands rejected as being anticipated by Moorehead U.S. Patent No. 4,983,168. Dependent claims 27-30 stand rejected over Moorehead alone or in view of other art. Finally, dependent claim 26 was rejected over Moorehead in view of Franzel U.S. Patent No. 5,782,817. However, claim 26, which recited a valve, has been canceled without prejudice. Instead, independent claims 21 and 25 have been amended to recite that subject matter. Accordingly, and because Franzel was cited for its valve (neither Whitney nor Moorehead having any such valve), Applicant will address these claims as if they had been rejected on the basis of either Whitney or Moorehead both in view of Franzel.

Even assuming that Whitney or Moorehead otherwise disclose the features of claims 21 and 25 (which is not conceded), Examiner acknowledges that neither disclose a valve at the proximal end of the tube. To this end, claims 21 and 25 recited that the valve is formed at the proximal end of the tube as part of the "single integral piece" with the tube and tab(s). By

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<sup>1</sup> Dependent claim 17 was rejected on the basis of Whitney and Orr, but Orr does not provide the missing hinge either. Hence, because claim 16 is patentable, claim 17 is likewise patentable rendering it unnecessary to further address the combination of Whitney and Orr. Applicants reserve the right to present specific arguments against that combination should it become necessary.

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contrast, the valve of Franzel is not formed as part of the introducer, but is a separate component added later. With reference to Figures 2 and 3 of Franzel, it is clear that the valve taught therein is a component separate from the tube of the introducer. Such a separate valve requires assembling the valve as a separate component, extra materials for making the separate valve, and additional assembly steps for inserting the valve into the introducer. All of these extra components, materials, and steps result in an increased cost to produce an introducer having the valve of Franzel. Since neither Whitney nor Moorehead disclose a valve, and since the valve of Franzel is not taught or suggested to be formed as part of the "single integral piece" of Applicants' invention, it is respectfully submitted that claims 21 and 25 (and thus the claims which depend therefrom) are patentable thereover.<sup>2</sup>

#### CONCLUSION

For the foregoing reasons, it is submitted that all claims are patentable and a Notice of Allowance is respectfully requested.

No fee is believed due with this submission. However, if any additional fee or surcharges are deemed due, please charge same or credit any overpayment to Deposit Account No. 23-3000.

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<sup>2</sup> While dependent claims 27-30 stand rejected over Moorehead in view of other art, that other art also does not appear to teach a valve, much less an integral valve. Hence, because claim 15 is patentable, claims 27-30 is likewise patentable rendering it unnecessary to further address the combinations of Moorehead and that other art. Applicants reserve the right to present specific arguments against those combinations should it become necessary.

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The Examiner is invited to contact the undersigned attorney with any questions or remaining issues. An Associate Power of Attorney has been submitted in this case, a copy of which is attached hereto as Exhibit B.

Respectfully submitted,

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